

Previous correspondence with OPP concerning the device

From: Liem.David@epamail.epa.gov
Sent: Thursday, April 28, 2005 2:25 PM
To: erauckman@charter.net
Subject: Device- Silver generating washing machine-RAUCKAM

Dear Mr. Rauckman:

This is in response to your question how the Silver Generating Washing Machine is regulated under FIFRA (Federal Insecticide Fungicide and Rodenticide Act).

The Antimicrobial Division of the EPA regulates the registration on the use, sale, distribution of antimicrobial pesticide products for certain inanimate hard non-porous surfaces or incorporated into substances under the pesticide law, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). You can check the definitions, terms including a pesticide at <http://www4.law.cornell.edu/uscode/7/136.html> A simplified definition is posted at <http://www.epa.gov/pesticides/about/index.htm>

Based on our phone conversation and the information in these two emails, the Silver Generating Washing Machine that you described is considered as a pesticidal device under FIFRA noted above with slight additional condition noted below. A device as defined under FIFRA, is any instrument or contrivance (other than a firearm) intended for trapping, destroying, repelling or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man and living animals) but not including equipment used for the application of pesticides [see FIFRA section 2(h)]. A device is not required to be registered under FIFRA section 3 (<http://www.epa.gov/pesticides/fifra.htm>). However, devices are subject to FIFRA law and regulations and subject to a number of other requirements, such as registering the establishment in which the device is produced, maintenance of annual production records, proper labeling, as well as appropriate product (device) labeling that is not false and misbranded. Pesticidal devices which make public health claims and are inefficacious would be of concern and in these cases appropriate enforcement and regulatory actions, within FIFRA authority, will be considered, and efficacy data are required to demonstrate that it is effective as claimed.

Also, it should be noted, that, if the article incorporates a substance or mixture of substances (chemicals) intended to prevent, destroy, repel or mitigate any pest, it (chemical or mixture of chemical) is considered to be a pesticide and as such is subject to registration under FIFRA section 3.

Here are some examples of devices subject to FIFRA section 2(q)(1) (proper labeling) and section 7 (registration of establishments) regulation (see 41FR51065 of November 19, 1976), include but not limited to the following:

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- o Certain ultraviolet systems, ozone generators, water filters and air filters (except those containing substances which are pesticides), and ultrasonic devices for which claims are made to kill, inactivate, entrap, or suppress the growth of fungi, bacteria, or viruses in various sites;

- o Certain high frequency sound generators, carbide cannons, foils, and rotating devices for which claims are made to repel birds;

- o Black light traps, fly traps, electronic and heat screens, fly ribbons, and fly paper for which claims are made to kill or entrap certain insects; and

If you sell and marketed the "silver electrode kit" in the washing machine your device will fall within the definition of a device under FIFRA, then what you need to do is to obtain an EPA establishment number, reporting, keeping books and records, etc. by contacting U.S. EPA Region where you are manufacturing the device and ask for an establishment number (EPA Form 3540-8). You can contact the HQ by contacting Ms. Michelle Stevenson at 202-564-4203 or stevenson.michelle@epa.gov. Or visit the following website: <http://www.epa.gov/oeca/datasys/instruct8.pdf>

However, if you also sell and or distribute the silver bars that are retrofitted in to the "silver electrode kit" separately, then this silver bar is subject to regular registration under FIFRA section 3 under FIFRA. This is addition of filing the "Electrolytic Silver Kit" as a device under FIFRA.

Please note that the labeling requirements noted above and you need to comply that the label is not false and misbranded must comply with the requirements noted above. For example the statement such as "The anti-bacterial claims are: "Inhibits bacterial growth on washed fabric" and "Reduces bacterial and fungal populations in the washer" are not acceptable, since this statement is considered too broad and imply a public health claim; this claim will subject to an additional efficacy data requirement. You need to change with a claim to for example with "reduces odor causing microorganism" which means non-public health microorganisms.

Please note, for devices under FIFRA, although you do not need to submit the testing data for EPA's review and evaluation, you must save and keep all the test reports, in the event regulators want to see, verify and scrutinize all the claim that you claim on the device label.

Sincerely,
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Forwarded by David Liem/DC/USEPA/US on 04/18/2005 07:21 AM -----

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